

## REMARKS

The Office Action of July 30, 2009, has been received and reviewed. The claims are to be amended as previously set forth. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

### Rejections under 35 U.S.C. § 102(b)

Claims 1, 3-6, 8, 9, 13, 22, and 24-26 stand rejected under 35 U.S.C. § 102(b) as assertedly anticipated by Krone *et al.* (U.S. Pat 5,391,696) (hereinafter “Krone”) as evidenced by Lewis (U.S. 5,838,571) (hereinafter “Lewis”). Applicants have amended the claims and partially in view thereof traverse the rejections as hereinafter set forth.

Unless a single prior art reference describes “all of the limitations claimed” and “all of the limitations [are] arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). A single prior art reference must “clearly and unequivocally” describe the claimed invention “without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Id.* at 19 (citing *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)). Applicants respectfully assert that claims 1, 2, 4, 10, 12, and 20 cannot be anticipated by Krone as Krone does not describe all of the elements claimed.

Applicants note that claims 1, 24, and 26 have been amended herein to recite “wherein the pulsatile manner includes a lag phase of a predetermined time.” Basis for the amendment to claims 1, 24, and 26 can be found throughout the Specification and in at least ¶¶ [0002], [0006], [0025], [0054], [0056], and [0057], as well as in FIGs. 1-3. Krone in view of Lewis cannot anticipate amended claims 1, 24, and 26, as Krone in view of Lewis does not expressly or inherently describe a predetermined time for a lag phase in release of a pharmaceutical composition. In addition, Krone in view of Lewis does not teach the presence of a lag phase for drug release by polytartrate compositions – only an initial burst followed by further release. For at least the foregoing reasons, applicants request withdrawal of the rejections of amended claims 1, 24, and 26 under 35 U.S.C. § 102(b) and reconsideration of same.

In addition, Krone in view of Lewis cannot anticipate claims 3-6, 8, 9, 13, 22, and 25,

*inter alia*, as each of these claims depends from one of non-anticipated amended claims 1 and 24. For at least the foregoing reasons, applicants request withdrawal of the anticipation rejections.

### **Rejections under 35 U.S.C. § 103(a)**

Claims 1-19 and 21-26 stand rejected under 35 U.S.C. 103(a) as assertedly obvious over Krone in view of Lewis and in further view of Suzuki *et al.* (U.S. 6,015,789) (hereinafter “Suzuki”) and Remington’s Pharmaceutical Sciences 1990 18<sup>th</sup> ed., ch. 89 (hereinafter “RPS”) (collectively hereinafter “the references”). Applicants have amended the claims and partially in view thereof respectfully traverse the rejections as hereinafter set forth.

To establish a *prima facie* case of obviousness, the prior art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. Additionally, the Examiner must determine whether there is “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Further, rejections on obviousness grounds “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id* at 1741, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). “Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed . . . . To facilitate review, this analysis should be made explicit.” *Id*. Furthermore, to establish a *prima facie* case of obviousness there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742.

Applicants note that claims 1, 24, and 26 have been amended herein to recite “wherein the pulsatile manner includes a lag phase of a predetermined time.” Claim 14 has been amended to recite “determining a time length of the lag phase in the release of the pharmaceutically active material from the compressed tablet.” Basis for the amendment to claim 14 can be found


throughout the Specification and in at least ¶¶ [0002], [0006], [0025], [0054], [0056], and [0057], as well as in FIGs. 1-3. The references cannot render obvious amended claims 1, 14, 24, and 26, as the neither references themselves nor the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention taught or suggested a polytartrate composition having “a lag phase of a predetermined time” in the release of a pharmaceutical composition as recited by amended claims 1, 24, and 26 or actually “determining a time length of the lag phase” as recited by amended claims 14. For at least the foregoing reasons, applicants request withdrawal of the rejections of claims 1, 14, 24, and 26 under 35 U.S.C. § 103(a) and reconsideration of same.

In addition, applicants submit that the references cannot render obvious claims 2-13, 15-19, 22, 23, and 25, *inter alia*, as each of these claims depends from or otherwise incorporate all of the limitations of one of non-obvious amended claims 1, 14, and 24. In view of at least the foregoing, applicants request withdrawal of the rejections of claims 2-13, 15-19, 22, 23, and 25 under 35 U.S.C. § 103(a) and reconsideration of same.

### **CONCLUSION**

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants’ attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Dan Morath', with a long horizontal flourish extending to the right.

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